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Shoulder simulator wear test of five contemporary total shoulder prostheses with three axes of rotation and sliding motion

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Keywords: Shoulder simulator; Total shoulder prostheses; Wear test; Polyethylene.

ABSTRACT

Shoulder joint replacement generally utilizes ultra-high molecular weight polyethylene (UHMWPE) as a bearing surface. Long term survival of such implants is recognized to be limited by wear of the UHMWPE. Commercially available JRI 42mm diameter VAIOS Total shoulders were wear tested in diluted bovine serum for five million cycles in a unique Shoulder Wear Simulator. Five Total shoulders were subject to rotational and translational motion, and loading, to replicate the 'Mug to Mouth' activity of daily living. A sixth Total shoulder was subject to loading only in a control station. Wear was measured gravimetrically and surface roughness was measured with a non-contacting profilometer. Mean wear rate of the UHMWPE components was 21.5 ± 5.4 mm^3/million cycles. The humeral heads roughened, from 19 ± 3 nm Sa to 43 ± 13 nm Sa over the five million cycles of the test, whilst the UHMWPE glenoid components became smoother, from 959 ± 230 nm Sa to 77 ± 17 nm Sa. This is the first reported wear test of multiple samples of a commercially available Total shoulder in a dedicated shoulder simulator.

INTRODUCTION

Shoulder joint replacement (SJR) is the third most common orthopaedic joint replacement after hip and knee joint replacement in England and Wales[1], and data suggests that primary SJR is growing exponentially[2, 3]. There are two main types of SJR. Total shoulders are anatomically correct and typically have differing humeral and glenoid component spherical diameters allowing both rotation and sliding of the joint. Reverse shoulders are anatomically inverted and have similar humeral and glenoid diameters giving a conforming geometry, akin to ball and socket joints, and are intended to operate with a largely rotational motion. Most SJRs generally employ a Cobalt Chromium (CoCr) component rubbing against ultra-high molecular weight polyethylene (UHMWPE) as an articulation.

It is recognized that implants using UHMWPE are limited in their longevity by wear of the UHMWPE and the body's reaction to UHMWPE wear debris[4]. Wear of the polyethylene glenoid component elicits an osteolytic response to the wear particles, leading to aseptic loosening of the joint. This has been established through numerous studies of Total shoulders, spanning many years. A study in 1999[5] examined the membranes surrounding Total SJR revised for aseptic loosening associated with osteolysis, and found UHMWPE wear particles. A subsequent study in 2001 of 39 Total shoulder glenoid components found that 97.2% were loose[6]. A review published in 2008 recognized that glenoid component failure was the most common complication in Total SJR[7].

To investigate SJR wear *in vitro*, the Newcastle Shoulder Wear Simulator was designed, commissioned and validated[8, 9]. It is the first multi-station shoulder simulator capable of applying physiological motion in three axes with physiological loading. It is fully programmable allowing it to reproduce shoulder activities of daily living (ADLs). For example, lifting an object to head height, or drinking from a mug[10].

In a previous study, the Newcastle Shoulder Wear Simulator was used to wear test commercially available JRI Orthopaedics 42mm diameter Reverse VAIOS shoulders using three axes of physiological motion with physiological loading[9]. The loads and motions associated with the ‘mug to mouth’ activity of daily living were applied and a wear rate of 14.3mm^3/million cycles was measured[9]. However, total shoulders are designed to allow the translational motion seen in the natural glenohumeral joint[11]. In the current study, in addition to applying the loads and motions associated with ‘mug to mouth’, a translational sliding motion was therefore added to the simulator to wear test commercially available JRI Orthopaedics 42mm diameter Total VAIOS shoulders (see Figure 1).

Figure 1: JRI Orthopaedics Total VAIOS shoulder Joint Replacement. To the upper left is the UHMWPE glenoid component with its titanium backing. To the right is the humeral component, with the CoCr head atop a titanium stem.

Previous shoulder simulators[12-16] offered limited statistical value having been single station machines. Other Total shoulder implant wear tests have employed knee simulators[17, 18] with limited ranges of motion compared to those available at the human glenohumeral joint. Nevertheless, it is worth considering the results of previous Total shoulder wear tests.

A single station test machine was used to apply motion in the abduction-adduction axis alone[13]. Such simplification of motion to one axis[19], or application of a linear wear path[20], has been shown to produce negligible wear levels in UHMWPE hip joints and therefore give non-clinically relevant results. This same single station test machine was also used in a later study[15] and the results were inconsistent between the studies. Geary et al[14] used a different single station machine with two axes of motion to wear test Total shoulders. However, the joints were mounted in Sawbone which prevented gravimetric wear measurement.

Dieckmann et al[16] used a single station simulator to wear test a 54mm diameter commercially available (Capica, Implantcast) Titanium Nitride (TiN) coated titanium humeral head against an UHMWPE glenoid. The simulator featured two axes of applied motion, dynamic loading, and a third axis which allowed longitudinal motion resisted by a spring. The maximum translational displacement was given as 'about ± 0.7' without units. After 5 million cycles, average wear of the glenoid was 9.9 mm^3/ million cycles when converted to a mean volumetric wear rate. An AMTI knee simulator was used to test 48mm diameter CoCr humeral components against UHMWPE glenoid components with ‘abduction-adduction rotation’, sliding translation and a constant load of 756N[17].

Wirth et al also tested three 48mm diameter CoCr humeral components against cross-linked polyethylene (XLPE)[17]. Using a density of 930 kg/m^3 for XLPE[21] to convert the gravimetric results to volumetric results, the study measured a wear rate of 7.5 mm^3/million cycles compared with 49.4 mm^3/million cycles for UHMWPE. That XLPE should give a lower wear rate compared with UHMWPE is to be expected[22]. In a separate study, six XLPE glenoid components were articulated against 44mm diameter CoCr humeral components with both rotation and translation in an MTS knee simulator[18].

METHODS

The Newcastle Shoulder Wear Simulator[8, 9] has five articulating stations and one static control station. Axial loading to each implant is applied using a pneumatic cylinder, the compressed air to these six cylinders being supplied equally from a proportional valve via a manifold. Three other pneumatic cylinders with integral position encoders move five glenohumeral prostheses simultaneously in the flexion-extension, abduction-adduction, and internal-external rotation axes. A mechanism with a rotational centre eccentric to the internal-external axis, and driven by the internal-external motion, was built into the components between the loading cylinder and lubricant bath to provide translational sliding motion to each test station. The simulator is programmed in LabView and National Instrument controllers are used to control the pneumatics.

'Mug to Mouth' was chosen as the ADL to use in this wear test as this was used in a previous wear test of reverse shoulders[9] and thus allowed a direct comparison. Rotational motion ranges per cycle were -16° to +11° in flexion-extension, -18° to -6° in abduction-adduction, and -42° to -17° in internal-external rotation. Joint rotations and loads mimicked those in the previous test of Reverse shoulders[9]. A cadaveric study of glenohumeral mechanics[11] measured a mean range of translation of 3.5 ± 1.0mm. Hence, 3.4 mm of translational sliding was applied each cycle in the shoulder simulator, in an arc approximately in the abduction-adduction direction. The offset of the centre of rotation was 9mm. The various motions applied in the simulator test are shown in Figure 2. Dynamic loads applied over each cycle ranged between approximately 180N to 250N[9]. These are shown in Figure 3.

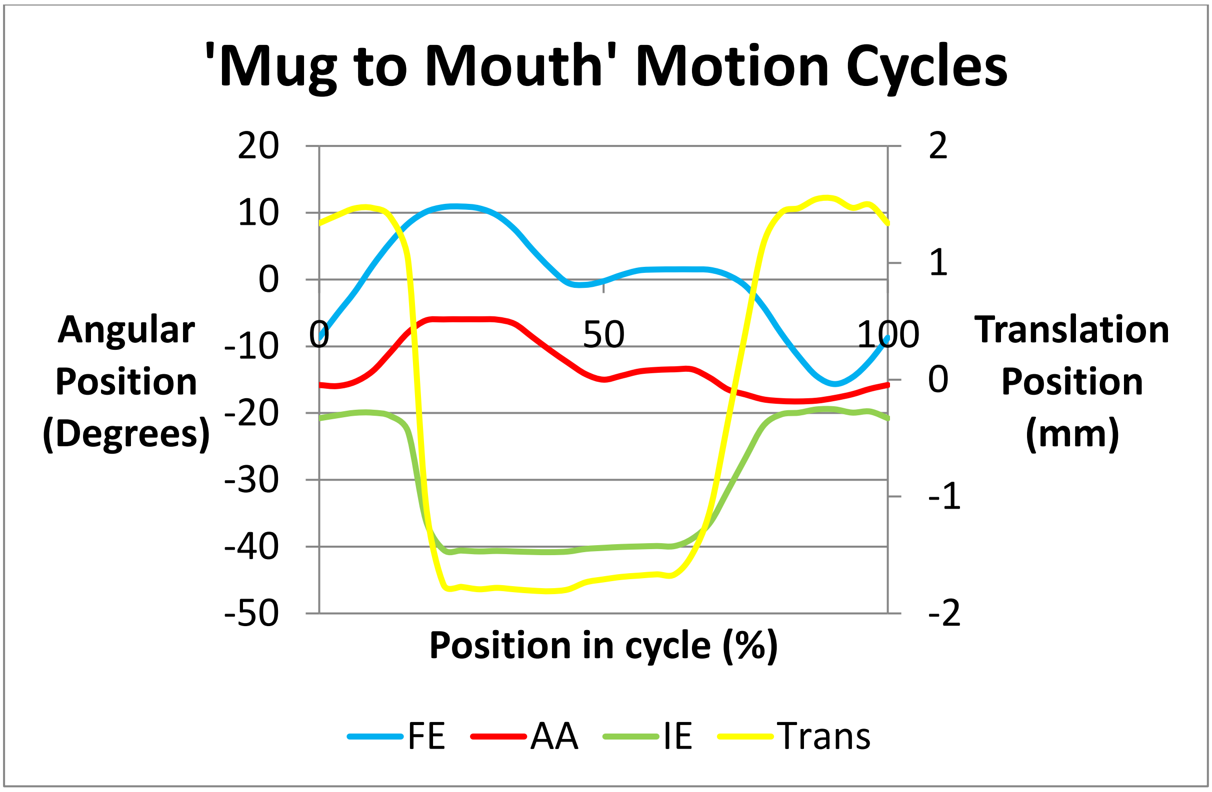

Figure 2: Motions applied in the shoulder simulator for testing Total shoulder prostheses. FE = flexion/extension; AA = abduction/adduction; IE = internal-external rotation; Trans = translational.

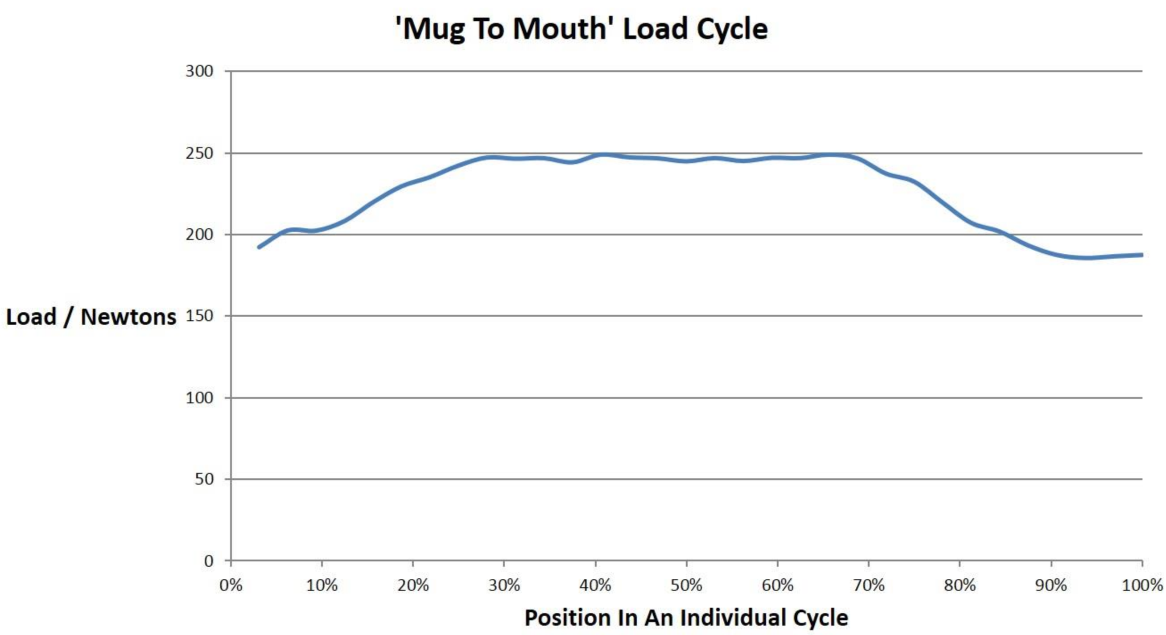

Figure 3: Loading applied in the shoulder simulator during ‘mug to mouth’

A 5 million cycle wear test was performed with JRI Orthopaedics Total VAIOS shoulders. These consist of a CoCr humeral head articulating against an UHMWPE glenoid component. Five 42 mm diameter Total shoulders were wear tested and a sixth was subject to dynamic loading in the ‘control’ station. The lubricant employed was newborn calf serum diluted to give a protein content of 26 g/l, maintained at ambient temperature. Twenty-six g/l was chosen to match previous test work using the shoulder simulator[9]. Moreover it fits well with other guidance which has been summarised elsewhere and suggests: above 20 g/l; in the range 20-35 g/l; and ‘about 30 g/l’[23]. In regard to ambient temperature, it has been seen that protein precipitation, which reduces wear, occurs at higher temperatures[24]. In addition, temperatures around ambient produced clinically valid wear[25]. Gravimetric measurements (Denver Instruments TB-215D, sensitivity 10µg) were used to determine the weight change and thus the wear of components. At regular intervals the simulator was stopped, lubricant was decanted, test components were carefully removed, cleaned and weighed to a consistent protocol. The gravimetric method was based on ISO 14242-2 for testing hip prostheses[26], in the absence of a similar ISO protocol for shoulder prostheses. Using a density of 938 kg/m^3 for the UHMWPE, volumetric wear was then calculated from weight losses, which were compensated by any weight changes of the control. Roughness measurements of the articulating surfaces of the prostheses were obtained using a ZYGO NewView 5000 non-contacting profilometer[27]. Ten measurements were taken per component and the mean roughness average (Sa) calculated.

RESULTS

The mean wear results for the UHMWPE components of the Total shoulders are shown in Figure 4. As can be seen, the results were linear over the 5 million cycles of testing. A mean ± S.D. wear rate of 21.5 ± 5.4 mm^3/million cycles was measured.

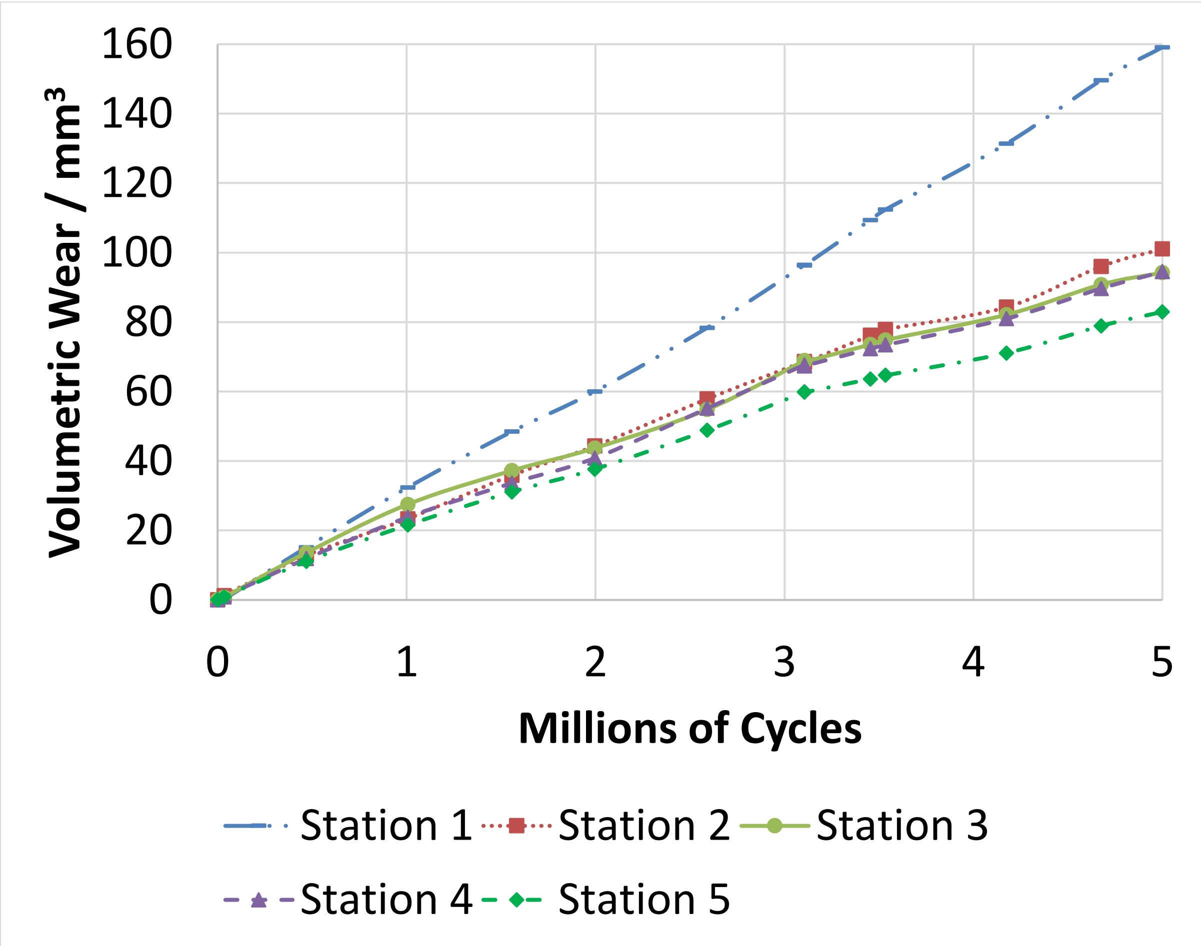

Figure 4: Wear results for the five JRI VAIOS Total shoulders

In Table 1, the surface roughness measurements, Sa, of all the CoCr humeral heads and UHMWPE glenoid cups are given at zero cycles, prior to testing, and at 5.0 million cycles after wear testing. The mean ± S.D. values are also given. The CoCr humeral heads roughened, from 19 ± 3 nm Sa to 43 ± 13 nm Sa over the duration of the test, which was statistically significant (p=0.013). The UHMWPE glenoid components became smoother, from 959 ± 230 nm Sa to 77 ± 17 nm Sa over the duration of the test, and this was also statistically significant (p=0.001).

Station	CoCr Humeral head zero cycles Sa (nm)	CoCr Humeral head 5,000,000 cycles Sa (nm)	UHMWPE Glenoid cup zero cycles Sa (nm)	UHMWPE Glenoid cup 5,000,000 cycles Sa (nm)
1	13	56	1064	73
2	22	32	1288	51
3	20	59	954	74
4	20	31	779	92
5	19	37	712	93
Mean ± S.D.	**19 ± 3**	**43 ± 13**	**959 ± 230**	**77 ± 17**

Table 1: Surface Roughness measurements of the five CoCr humeral heads and five UHMWPE glenoid cups at zero cycles prior to testing and after 5,000,000 cycles of wear testing.

An image of the surface of the unworn humeral head from station 3 taken prior to testing using the Zygo profilometer is shown in Figure 5.

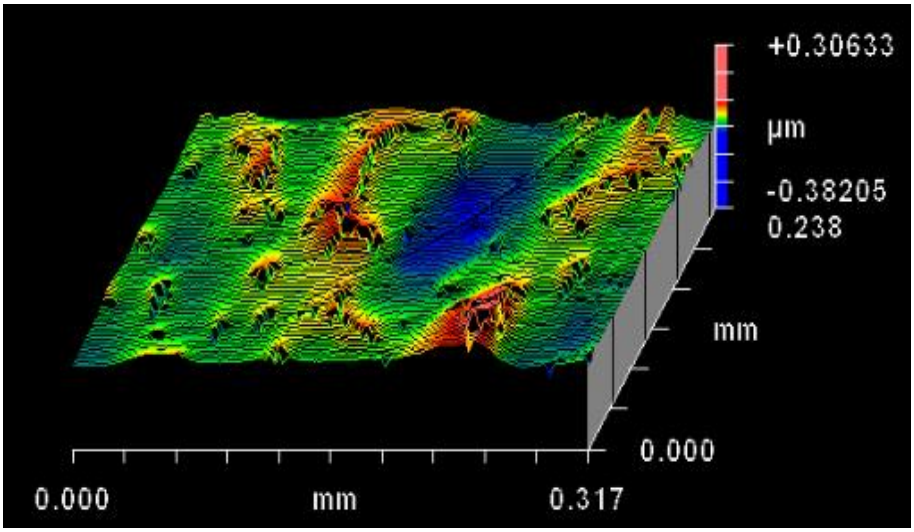

Figure 5: An image of the surface of the unworn humeral head from station 3, Sa = 20 nm, taken prior to testing using the Zygo profilometer.

This contrasts with Figure 6 for the same component taken after 5 million cycles of testing, where numerous irregular scratches can be seen.

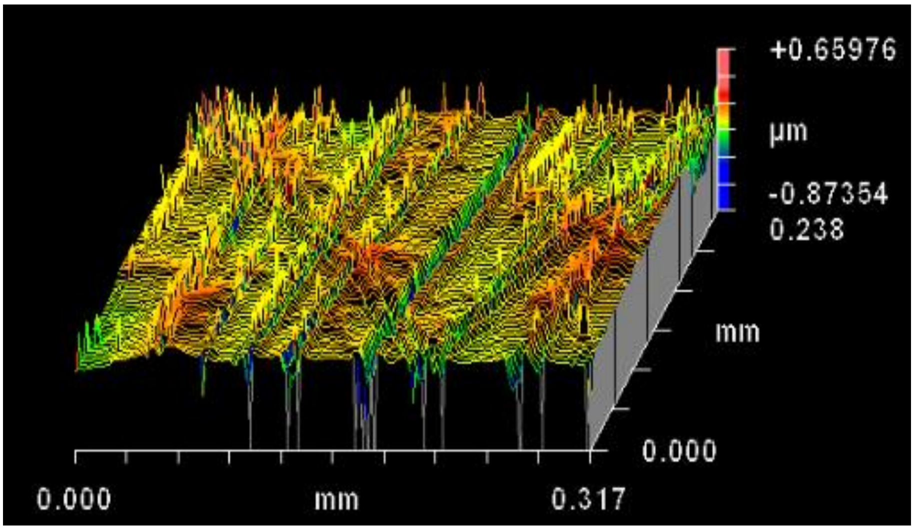

Figure 6: An image from the Zygo profilometer of the surface of the same humeral head from station 3, Sa = 59 nm, taken after 5 million cycles of testing. Note numerous irregular scratches.

Figure 7 is an image of the paired glenoid component prior to testing, with regular, parallel machining marks in the UHMWPE.

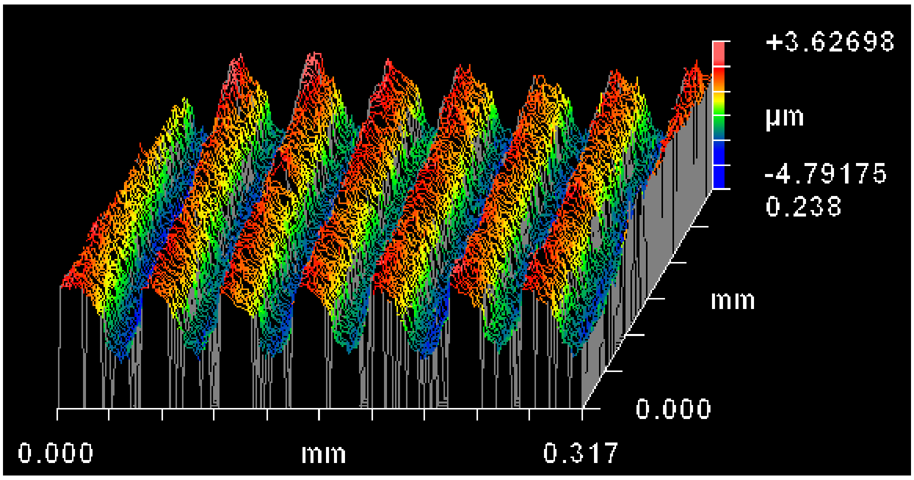

Figure 7: An image taken on the Zygo profilometer prior to testing of the glenoid component from station 3, Sa = 954 nm. Note the regular, parallel machining marks in the UHMWPE.

The surface of the same glenoid component is shown in Figure 8 after 5 million cycles of wear testing. The machining marks are no longer evident and the surface is an order of magnitude smoother than prior to testing.

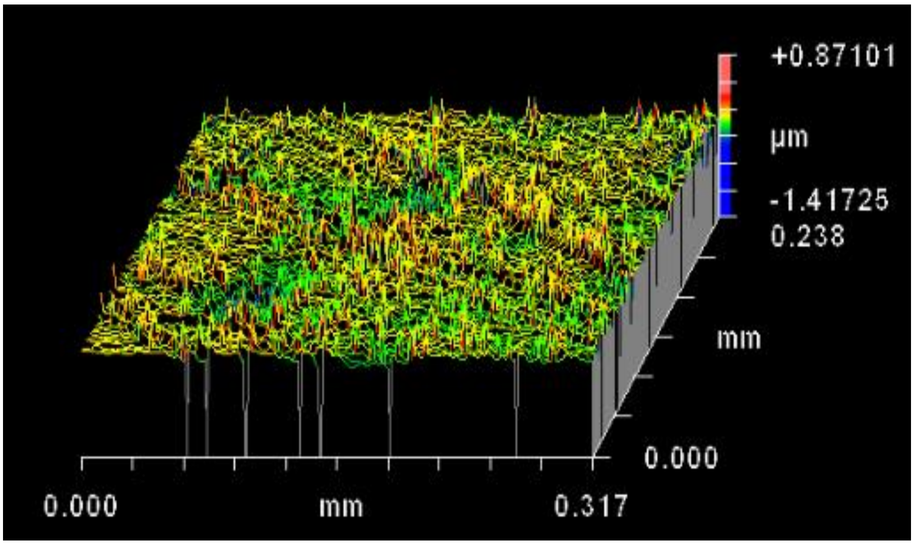

Figure 8: The surface of the same glenoid component from station 3 after 5 million cycles of testing. The machining marks are no longer evident and the surface roughness is an order of magnitude smoother than prior to testing, Sa = 74 nm.

DISCUSSION

Our hypothesis was that, due to the additional translational motion, wear rates would be increased compared with a previous Reverse shoulder test where only rotations were applied[9]. The wear rate of Reverse VAIOS shoulders over 4.5 million cycles was 14.3 ± 1.6 $mm^3/10^6$cycles. The Total VAIOS shoulders, tested with the addition of translational motion, exhibited a 50% larger wear rate (21.5 ± 5.4 $mm^3/10^6$cycles) compared with the Reverse shoulders. An explanation for the increase in wear rate of Total shoulder joints over Reverse shoulder joints is likely the application of translational sliding, resulting in more complicated motion paths in the Total shoulder wear test. Further work may validate this explanation, or give reason to consider other explanations. Due mainly to the sample size, the difference in wear results is not quite statistically significant at 95% (p=0.068). From Figure 4 it is clear that the UHMWPE test component in station 1 showed higher wear than in the other stations. All components were of the same size and made to the same specification, so there were no differences in this regard. In terms of CoCr component roughness, the component in station 1 did not show the highest roughness so again this does not provide an explanation. While no final explanation is currently available, it should be noted that such differences in wear rates between stations have been seen in simulator studies of metal on polymer bearings[28, 29]. A comparison of the wear results at the end of this study of Total shoulders and the previous study of Reverse shoulders is given in Table 2.

	Total shoulders with sliding	**Reverse shoulders without sliding**
Wear rate	21.5 ± 5.4	14.3 ± 1.6

(mm^3/million cycles)		
CoCr roughness, Sa (nm)	43 ± 12	36 ± 12
UHMWPE roughness, Sa (nm)	77 ± 17	258 ± 74

Table 2: Comparison of results and final measurements from this study of Total shoulders with rotation and sliding motion and a previous study of Reverse shoulders with rotation only (Smith et al, 2015)[9]

As can be seen from Table 2, surface roughness values for the CoCr components show good agreement across the Total and Reverse tests. The surface roughness for the UHMWPE components both before and after testing were different. However, both sets of UHMWPE components had become smoother over the course of testing. This smoothing is expected if comparison is drawn with UHMWPE surface roughness changes in knee simulator testing[30] for the Total shoulders due to the similar combination of rotational and translational sliding motion. Similarly, comparison with smoothing of UHMWPE in the Reverse shoulders may be drawn with hip simulator testing[31] as both are subject only to rotational motion.

From testing the Total shoulders, the CoCr humeral heads roughened significantly (p=0.026) over the course of the wear test, Sa increasing from 19 to 43 nm. The wear rates of the UHMWPE glenoid cups were linear over the course of the wear test, suggesting that this roughening did not impact on the wear rate of the UHMWPE. Comparison cannot be drawn with the other reported Total shoulder studies, as only Dieckmann et al[16] reported roughness data. However, the latter study did not use a CoCr humeral head and therefore comparison with those measurements is inappropriate. The authors are unaware of any studies reporting clinical surface roughness measurements of explanted Total shoulders. Replacement knee joints are subject to both rotational and translational motion and hence might be used to draw comparison with Total shoulders. Explanted and new CoCr knee replacements have been measured[21, 32] and surface roughness is greater with explanted prostheses, being 130 nm Sq (root mean square surface roughness) compared with 30 nm Sq for unworn[21]. This increase in roughness fits with the increase in Sa which we measured. Roughening of CoCr femoral knee components articulating against UHMWPE has also been reported in a simulator study[30]. Hence, the roughening of the CoCr humeral heads over the course of the wear test in this study might be expected.

Smoothing of the UHMWPE glenoid components in this study shows broad agreement with other studies. The UHMWPE glenoid cups became significantly ($p=0.001$) smoother over the wear test, Sa reducing from 959 to 77 nm. The single specimen Total shoulder simulator study by Dieckmann et al[16] reported smoothing of the UHMWPE glenoid from 250nm to 30nm. Again, the authors are unaware of clinical studies of shoulders which have measured similar surface roughness parameters. Similarly, the authors are unaware of published clinical studies for the articulating surface of UHMWPE tibial trays from knee prostheses. However, unpublished data of such measurements by one of the authors (EK) found polished regions of *ex-vivo* tibial trays to be smoother than those of new prostheses. Smoothing of UHMWPE tibial trays has also been observed in a knee simulator study[30].

A summary of this study and the various multiple station Total shoulder wear tests discussed in the Introduction are shown in Table 3. This and the other studies all report linear relationships between wear volume and number of cycles, and therefore offer one strong area of comparison.

Author	**Simulator**	**Load**	**Motion**	**Prostheses**	**Results $mm^3/10^6$ cycles**
This study	Newcastle Shoulder Wear Simulator	Physio-logical 180 to 250N	Flexion-extension -16° to +12° Abduction-adduction +18° to -5° Internal-external rotation -42° to -17° Sliding translation 4 mm	5 x 42mm Total VAIOS CoCr v UHMWPE	21.5 ± 5.4
Dieckmann et al, 2013	'test control unit'	Max 500N Min 100N	Flexion-extension	1 x 54mm Total Capica	9.9

			+10° to -10° Abduction-adduction +35° to -35° Spring limited translation ‘about±0.7’ no units	TiAlVa coated with TiN v UHMWPE	
Wirth et al, 2009	AMTI knee simulator	Constant 756N	Abduction-adduction ±8° Sliding translation ±2mm Elevation 0° to 8°	3 x 48mm Humeral with 6mm Glenoid mismatch CoCr v UHMWPE	49.4
Wirth et al, 2009	AMTI knee simulator	Constant 756N	Abduction-adduction ±8° Sliding translation ±2mm Elevation 0° to 8°	3 x 48mm Humeral with 6mm Glenoid mismatch CoCr v XLPE	7.5
Mummert et al, 2016	MTS knee simulator	Constant 756N	Abduction-adduction	6 x 48mm Global Advantage	3.5 ± 0.9

	Sliding translation Forward elevation	Total Shoulders CoCr v XLPE

Table 3: Simulator wear studies of Total shoulders.

The results of this study bear good comparison with the various studies when accounting for load, joint diameter and material. For example the 21.5 mm^3/million cycles measured in this study does not initially appear to show good agreement with the 49.4 mm^3/million cycles reported by Wirth et al[17], with the latter being 2.3 times greater. However, CoCr joints articulating against UHMWPE operate in a mixed lubrication regime[33, 34]. The mixed lubrication regime between CoCr and UHMWPE is one where the majority of the load across the joint is carried by asperity contact. When the majority of the load is carried by asperity contact, wear of the joint is typical of a boundary lubrication regime. For joints operating in a boundary lubrication regime, the Lancaster[35] wear equation is applicable

$$V=kPx$$

where V, the volume of material removed by wear, is proportional to the product of wear factor, k, applied load, P, and sliding distance, x. Therefore, as load increases, wear should increase proportionally. Similarly, as sliding distance increases, wear should increase, and sliding distance increases with increasing joint diameter. Detailed wear path analysis is beyond the scope of this work, however, simple comparison of loads and joint size with other studies is appropriate. The Wirth et al study[17] used larger (48mm) diameter joints, than the 42mm diameter in this study.

The load was also larger, 756 N versus 250 N. Adjusting the wear rate of 21.5 mm^3/million cycles by a factor of 48 mm over 42 mm for joint size, and a factor of 756 N over 250 N for load, gives an adjusted wear rate of 72.8 mm^3/million cycles. Comparison of this adjusted wear rate with the 49.4 mm^3/million cycles from the Wirth et al study shows reasonable agreement in the absence of more detailed analysis of the differing wear paths. Equally however, this calculation could indicate that the Newcastle shoulder simulator, under the complex motions that it is capable of applying, gave the greatest wear compared with other tests of Total shoulders undertaken in simulators. Once such data becomes available, validation against wear volumes of shoulder explants will probably give the definitive answer to what is the 'true' wear of an artificial shoulder joint. Until then, we caution that the complex motions applied by the Newcastle shoulder simulator may more accurately predict wear and that the simplified motions and loadings used in other, non-shoulder simulators could underestimate wear. Certainly, recent orthopaedic history, namely the debacle of metal-on-metal hip joints, has shown that wear and its devastating impact on the human body should never be underestimated[36-38].

While this study advanced our understanding of rotational and translational loading regimes applied to TSR, it is not without limitations. A limitation of this study may be the apparently low applied loads replicated in the 'Mug to Mouth' ADL. However, by using the 'Mug to Mouth' ADL, direct comparison with the previous Newcastle Shoulder Wear Simulator testing of Reverse shoulders was possible. Having completed wear studies on Total and Reverse shoulders with the 'Mug to Mouth' ADL, future wear studies will include other ADLs with higher loads, for example, 'lift shopping bag'[39]. The sample size of five may be considered small but this is actually a greater number than any other tests of Total shoulder joints aside from the six reported recently in a conference paper by Mummert et al[18]. That a single size of implant was tested may be considered a limitation. However, as can be seen from Table 4, this is typical of artificial joint testing. Moreover, as metal-on-polyethylene implants generally work under boundary or mixed lubrication, it is relatively straightforward to extrapolate wear results from one size to other sizes. Indeed, this computational wear analysis has been done for artificial shoulder joints[40, 41]. Another limitation is that we have assumed that all the wear is from UHMWPE, rather than UHMWPE and CoCr. However, this assumption is based on the common finding in biotribologcal studies that there is no discernible wear of the hard metal component compared with the softer polyethylene[22, 42].

A wear test of Total shoulders was completed with both rotational and sliding motions. The wear rate and linear relationship of wear volume with increasing cycles shows good agreement with other studies of Total shoulders tested in knee simulators. Surface roughness measurements showed that the CoCr humeral heads roughened over the course of the wear test. This showed agreement for *ex-vivo* and simulator knee studies, which likely give the closest approximations given the lack of data specifically related to Total shoulders. The UHMWPE glenoid components in this study became smoother over the course of the wear tests, showing agreement with shoulder and knee simulator studies.

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Conflict of interest statement

None

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